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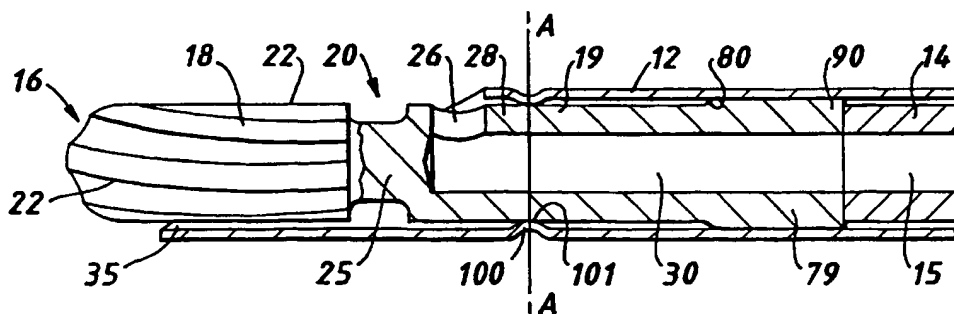
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(54) Title: **SURGICAL TOOL CONTAINMENT DESIGN FOR SURGICAL INSTRUMENTS**



(57) Abstract: A surgical instrument (10) includes an outer tube (12) having an open distal end (20) and a first radially extending surface (101); and an inner member (14) positioned to move within the outer tube (12) and having a surgical tool (16) and a second radially extending surface (80). The first radially extending surface (101) and the second radially extending surface (80) are positioned to contact each other to maintain the surgical tool (16) within the central bore if the surgical tool (16) separates from the inner member (14).

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## **SURGICAL TOOL CONTAINMENT DESIGN FOR SURGICAL INSTRUMENTS**

This invention relates to endoscopic surgical instruments, and  
5 in particular to powered endoscopic surgical instruments for, e.g.,  
endoscopic sinus surgery.

Powered endoscopic surgical instruments often include a  
stationary outer tube surrounding an inner tube that carries a  
10 surgical tool on its distal end and is rotated by a motor. Body tissue  
exposed to the surgical tool through an opening in the outer tube is  
cut by the rotating tool. Tissue fragments cut by the tool and  
irrigating fluid from the surgical site are drawn through an interior  
suction passage extending through the inner tube in response to  
15 applied suction. Such instruments are described in U.S. Pat. Nos.  
4,203,444, 4,274,414, 4,834,729, 4,842,578, 4,983,179, and  
5,322,505, all of which are incorporated herein by reference.

The configuration of the endoscopic surgical tool is typically a  
20 function of the type of body tissue to be cut. For example, in  
instruments for cutting relatively soft tissue (such as cartilage and  
mucosal tissue), the tool is a blade formed by sharpened edges of a  
window in the inner tube which cooperates with sharpened edges of  
the outer tube opening (which is generally side-facing) as the inner  
25 tube rotates.

In other configurations, the distal end of the instrument is open  
and the burr is used for both side and head-on cutting. An example  
of an instrument of this type is described in the above-referenced  
30 U.S. Patent No. 4,842,578. In these instruments, the burr may rub  
against the inside of the outer tube, which dulls the cutting edges as  
the surgeon applies non-axial pressure to the instrument. Because

of the high rotational speeds typically encountered in powered endoscopic surgical instruments (e.g., up to >7,000 rpm) and the open distal end, the burr can fracture from the rotating inner shaft of the instrument during use, and as a result may be jettisoned into  
5 the patient's body.

In a general aspect of the invention, a surgical instrument includes an outer tube having an open distal end, and a first radially extending surface positioned proximally at the open distal end in the  
10 bone; and an inner member positioned to move within the outer tube and having a surgical tool and a second radially extending surface. The first radially extending surface and the second radially extending surface are positioned to contact each other to maintain the surgical tool within the central bore if the surgical tool separates  
15 from the inner member.

A related aspect of the invention features a surgical tool having the second radially extending surface.

20 In essence, the retaining member serves as a mechanical stop to prevent the surgical tool (e.g., a shaving burr) from leaving the outer tube if the tool breaks free from the inner tube. Because the burr is maintained within the outer tube and not jettisoned into the surgical site, the risk of injury to the patient is reduced. This  
25 arrangement is particularly advantageous for surgical instruments which perform end-on cutting and, therefore, require an open distal end.

In another aspect of the invention, the invention features a  
30 method of manufacturing a surgical instrument with the following steps. An outer tube including an open distal end, a central bore,

and a first radially extending surface positioned proximally of the open distal end in the bone is provided. An inner member including a surgical tool and a second radially extending surface is also provided. The inner member is positioned within the outer tube so  
5 that the first radially extending surface and the second radially extending surface are positioned to contact each other to maintain the surgical tool within the central bore if the surgical tool separates from the inner member.

10       Embodiments of these aspects of the invention may include one or more of the following features. For example, in one embodiment, the first radially extending surface is positioned distal to the second radially extending surface. The outer tube includes a retaining portion having the first radially extending surface and the  
15 inner member includes a radially extending ridge having the second radially extending surface. The retaining portion includes a circumferential ridge. Alternatively, the retaining portion includes a number of protuberances or bumps, each circumferentially spaced from an adjacent protuberance.

20

In either case, the circumferential ridge and the protuberances may be integral to the outer tube. In certain embodiments, the retaining portion provides a bearing surface between the inner member and the outer tube to prevent the surgical tool from  
25 contacting the outer tube during use. Because the retaining portion maintains the inner member in spaced relationship with the outer tube, generation of excessive debris within the instrument and dulling of the cutting edges on the surgical tool is virtually eliminated, thereby improving the overall performance of the  
30 surgical instrument.

In other embodiments, the inner member includes a slot having the first radially extending surface and the outer tube includes a radially extending ridge disposed within the slot (which may provide a bearing surface). The outer tube includes a third radially  
5 extending surface positioned proximally (i.e., in the proximal direction) of the first radially extending surface and the inner member includes a fourth radially extending surface positioned proximally of the third radially extending surface. The inner member includes a circumferential ridge having the fourth radially extending  
10 surface.

The surgical tool includes a burr or other end-on cutting instruments. The inner member is adapted to rotate within the central bore of the outer tube.

15

Embodiments of the method of manufacturing the surgical instrument may include one or more of the additional features. The retaining portion is formed by corsetting the outer tube. Alternatively, the retaining member is formed by laminating a  
20 member to the outer tube.

Other features and advantages of the invention will be apparent from the drawings, the following Detailed Description, and the claims.

25

Fig. 1 is a perspective view of a surgical shaving instrument.

Fig. 2 is a side view, partially in cross section, of the surgical instrument, showing an inner tube carrying a burr at its distal end disposed within an outer tube.

30

Fig. 3 is an enlarged view of the distal end of the surgical instrument of Fig. 2, partially in cross section, showing the burr positioned within an axially elongated opening in the outer tube.

5        Fig. 4 is a cross-sectional end view of the surgical instrument of Fig. 3 about line segment A-A.

Fig. 5 is a partial side view of the surgical instrument of Fig. 3 which shows the burr broken free from the inner tube.

10

Fig. 6A is a side view of an alternative embodiment of a surgical instrument having laminated circumferential ridge and flared edge.

15        Fig. 6B is a cross-sectional end view of the surgical instrument of Fig. 6A about line segment A-A.

Fig. 6C is a cross-sectional end view of an alternative embodiment of a surgical instrument having an outer tube with bumps acting as a circumferential ridge.

20

Fig. 7 is a partial side view of the surgical instrument of Fig. 3 which shows dimensions used to calculate

25        Fig. 8 is a side view of another surgical instrument which shows multiple protuberances.

Fig. 9 is a side view of still another surgical instrument having a single protuberance.

30

Fig. 10 is a perspective view of a curved surgical shaving instrument.

Referring to Figs. 1-4, a surgical instrument 10, e.g., a shaver  
5 burr, includes an outer tube 12 which surrounds a rotatable surgical tool connected to an inner tube 14 and having an inwardly extending circumferential ridge 100. As will be described in greater detail below, circumferential ridge 100 acts as both a bearing surface on which a surgical tool, here a burr 16, rotates and a  
10 mechanical stop to prohibit the burr from leaving the outer tube if it breaks free from inner tube 14.

Burr 16 includes a fluted burr head 18 and a shank 19 having a enlarged proximal end 79 with an edge 80. Shank 19 is mounted,  
15 e.g., glued or welded, to a distal end of inner tube 14 rotatably disposed in outer tube 12. Burr head 18 is exposed to tissue through an opening 20 in the distal end of outer tube 12. The configuration of burr head 18 renders it suitable for cutting both bone tissue and softer tissue (such as cartilage and mucosal  
20 tissue). For example, burr head 18 includes axially elongated, inclined sharpened cutting edges 22 (see Figs. 1-2).

Burr head 18 is a solid distal extension of shank 19, which is tubular, and is connected to shank 19 by a tapered neck 25. An  
25 aperture 26 in an exterior wall 28 of shank 19 intersects a cylindrical interior chamber 30 in shank 19 for admitting tissue fragments and irrigating fluid into chamber 30. Inner tube 14 includes a suction passage 15 that communicates with chamber 30. During use, as inner tube 14 rotates, tissue exposed to burr head 18 is cut by  
30 rotating cutting edges 22, and the resulting tissue fragments and irrigating fluid are conveyed through aperture 26 into chamber 30.

Suction applied to passage 15 at a proximal end 32 of instrument 10 transports the tissue fragments and irrigating fluid proximally through inner tube 14 for removal from the body, while surgical instrument 10 remains in situ for further cutting. Outer tube 12 is rigidly mounted to a hub 34 at proximal end 33. Hub 34 rotatably receives a base 36 to which the proximal end of inner tube 14 is attached. Passage 15 terminates proximally in a suction port 40 in base 36. This construction is described, for example, in the above-discussed U.S. Pat. No. 5,322,505.

10

During use, proximal end 32 of instrument 10 is inserted into a handpiece (not shown), having a motor for engaging a proximal end 37 of base 36, which serves as a drive shaft for inner tube 14. Operation of the motor rotates inner tube 14 (and thus burr 16) within outer tube 12. (One example of such a handpiece is described in U.S. Pat. No. 4,705,038 which is incorporated by reference herein.)

As shown in Fig. 3, shaft 19 rotates about a surface 101 of circumferential ridge 100. Circumferential ridge 100 acts as a bearing to centrally position within and space the shaft and the burr head from the outer tube, thereby prohibiting the cutting edges 22 on burr head 18 from rubbing against an inner wall 35 of outer tube 12.

25

Referring to Fig. 4, circumferential ridge 100 is an integral ring of outer tube 12 that inwardly extends towards inner tube 19. The circumferential ridge can be formed as an integral part of outer tube 12 by corsetting the outer tube.

30



As shown in Fig. 5, in the event that shaft 19 separates, e.g., during surgery, from inner tube 14 at any point proximal to the extending edge 80, surface 101 of the circumferential ridge acts as a mechanical stop to contact the radially extending edge so that burr  
5 16 is maintained within outer tube 12 and not jettisoned out of surgical instrument 10 and into the patient's body.

Circumferential ridge 100 can be formed by a variety of processes. For example, the circumferential ridge can be formed as  
10 an integral part of outer tube 12 as described above or by laminating or welding a member 50 (See Fig. 6A) onto inner surface 35 of the outer tube.

Referring to Fig. 6B, member 50 can also be formed as a radial  
15 ring 102 within outer tube 12.

Referring to Fig. 6C, in other embodiments, a sufficient number of extending bumps 55 (here, eight) are circumferentially disposed and angularly spaced about the outer tube. A sufficient number of  
20 bumps 55 is required for centering the tool during rotation and for ensuring that the tool is maintained within the central bore of the outer tube if broken free from the rotating inner tube. The dimensions (width and height), shape, and location of the circumferential ridge from the distal end are also selected  
25 depending upon the dimensions of the outer tube, the inner tube, and the tool. Typically, the dimensions and location of the circumferential ridge can be determined geometrically.

Referring now to Fig. 7, assuming that the tool rotates about a  
30 center line (CL) and pivots about a point (Rp) on the surface of the circumferential ridge, the location and height of the circumferential

ridge are related to the dimensions of the outer tube and the tool.

For example, given a specific length of the tool (L) and a ridge height (Y1), the location of the circumferential ridge is calculated by using a simple triangular relationship which equates a distal triangle

- 5 A to a proximal triangle B. Triangles A and B are related by equation (1):

$$X1/Y1 = X2/Y2 \quad (1)$$

- 10 The ridge location (X1) is calculated by using the relationship between the tool length and ridge location ( $L = X1 + X2$ ), outer tube's inner diameter (D2), the dimensions of the tool, i.e., D3, D4, D5, the inner diameter at the ridge (D6), and the gap (D7) between the ridge and the tool when centered within the central bore. In this
- 15 particular case, i.e., when specifying the circumferential ridge height and tool length, X1 is the maximum distance that the circumferential ridge can be located from that tool's distal end. Alternatively, when specifying the length of the tool (L) and the ridge location (X1), the protuberance height (Y1) can also be calculated by using the same
- 20 triangular relationship and dimensions.

- In one embodiment, a surgical instrument has ridge height of 0.007 inches, a tool length of 0.842 inches, an inner diameter of the outer tube (D2) of 0.140 inches, an outer diameter of the tool
- 25 proximal end (D3) of 0.135 inches, and a distance between the circumferential ridge pivot point (Rp) and the tool (D7) of 0.001 inches. Accounting for manufacturing tolerances with these dimensions, X1 is 0.539 inches.

- 30 Burr head 18 and shank 19 can be made from any material compatible with surgery, e.g., hard plastics, ceramic, and metals.

Typically, the burr head, shank, and flared edge are an integral unit made from stainless steel (e.g., Type Stainless Steel 455) and hardened to a Rockwell hardness of at least 45. Alternatively as shown in Fig. 6A, the burr head and shank can be made as an  
5 integral unit and the flared edge can be formed, for example, by laminating a material 85 (e.g., plastic) about the proximal end of the tool. Burr 18 also can include a variety of cutting edges depending upon the type of tissue being cut or removed (bone vs. soft tissue). Examples of burr cutting edges are found in U.S. Patent Application  
10 Nos. 5,759,185 and 5,913,867 the entire contents of which are herein incorporated by reference.

Surgical instrument 10 is preferably disposable, that is, the device is made to be discarded after a single (or relatively few)  
15 uses. Outer tube 12 is made from stainless steel. Other materials may be used instead if, e.g., surgical instrument 10 is to be autoclavable and reusable. Additionally, the circumferential ridge and/or surgical tool can be coated with a solid lubricant (e.g., TEFLON®) or a liquid lubricant to reduce the friction between the  
20 tool and the circumferential ridge (bearing surface).

Referring now to Fig. 8, a surgical instrument 200 includes both a distal protuberance 150 and a proximal circumferential ridge 110 in an outer tube 155. Distal protuberance 150 is received within  
25 a circumferential slot 157 formed within a tapered neck portion 125 of burr 160. A surface 151 of distal protuberance 150 acts a bearing surface for tapered neck portion 125 of burr 160, thereby prohibiting the surface of burr head 180 from hitting an inner wall 135 of the outer tube during rotation. Circumferential ridge 110 is  
30 similar to ridge 100 discussed above. During catastrophic failure, both protuberance 150 and circumferential ridge 110 act as

mechanical stops prohibiting the burr from being jettisoned during catastrophic failure.

Alternatively, as shown in Fig. 9, surgical instrument 300  
5 includes a single protuberance 250 received within a circumferential slot 257 formed within a tapered neck region 225 of a burr 260. Single protuberance 250 acts as a bearing surface for tapered neck region 225 of burr head 280 and as mechanical stop for a burr 260.

10 The surgical instruments described above are useful in a wide variety of endoscopic procedures including arthroscopy. A surgical instrument 400, as shown in Fig. 10, including a circumferential ridge 470 is particularly well-suited for endoscopic sinus surgery. Unlike the surgical instrument 10 of Figs. 1-4, surgical instrument  
15 400 includes an outer tube 420 having a curved portion 410 for providing the surgeon with increased maneuverability when operating in a patient's sinus cavity. An inner tube 430 includes an inner flexible member 450 which connects on opposite ends 445, 465 to a proximal portion 440 and a distal portion 460, respectively.  
20 Inner flexible member 450 allows inner tube 430 to rotate within curved region 410 of outer tube 420. Circumferential ridge 470 prevents tool 500 from leaving outer tube 420 if the tool were to break free inner tube 430.

25 Still other embodiments are within the scope of the claims.

**CLAIMS**

1. A surgical instrument comprising:  
an outer tube including an open distal end, a central bore,  
and a first radially extending surface positioned proximally of the  
5 open distal end in the bone; and  
an inner member, positioned to move within the outer tube,  
including a surgical tool and a second radially extending surface,  
the first radially extending surface and the second radially extending  
surface being positioned to contact each other to maintain the  
10 surgical tool within the central bore if the surgical tool separates  
from the inner member.
2. The surgical instrument of claim 1, wherein the first radially  
extending surface is positioned distally of the second radially  
15 extending surface.
3. The surgical instrument of claim 2, wherein the outer tube  
includes a retaining portion having the first radially extending  
surface and the inner member includes a radially extending ridge  
20 having the second radially extending surface.
4. The surgical instrument of claim 3, wherein the retaining  
portion includes a circumferential ridge.
- 25 5. The surgical instrument of claim 4, wherein the  
circumferential ridge is integral to the outer tube.
6. The surgical instrument of claim 3, wherein the retaining  
portion includes a plurality of protuberances, each protuberance  
30 circumferentially spaced from an adjacent protuberance.

7. The surgical instrument of claim 6, wherein the plurality of protuberances are integral to the outer tube.
8. The surgical instrument of claim 1, wherein the retaining  
5 region provides a bearing surface between the inner member and the outer tube.
9. The surgical instrument of claim 1, wherein the inner member includes a slot having the first radially extending surface and the  
10 outer tube includes a radially extending ridge disposed within the slot.
10. The surgical instrument of claim 9, wherein the outer tube includes a third radially extending surface positioned proximally of  
15 the first radially extending surface and the inner member includes a fourth radially extending surface positioned proximally of the third radially extending surface.
11. The surgical instrument of claim 9, wherein the slot provides  
20 a bearing surface between the outer tube and the inner member.
12. The surgical instrument of claim 11, wherein the inner member includes a circumferential ridge having the fourth radially extending surface.  
25
13. The surgical instrument of claim 1, wherein the surgical tool includes a burr.
14. The surgical instrument of claim 1, wherein the inner member  
30 is adapted to rotate within the central bore of the outer tube.

15. A method of manufacturing a surgical instrument comprising:  
providing an outer tube including an open distal end, a  
central bore, and a first radially extending surface positioned  
proximally of the open distal end in the bone; and  
5 providing an inner member including a surgical tool and a  
second radially extending surface, and  
positioning the inner member within the bone of the outer  
tube so that the first radially extending surface and the second  
radially extending surface are positioned to contact each other to  
10 maintain the surgical tool within the central bore if the surgical tool  
separates from the inner member.
16. The method of claim 15, further comprising positioning the  
first radially extending surface proximally of the second radially  
15 extending surface.
17. The method of claim 16, further comprising providing the  
outer tube with a retaining region having the first radially extending  
surface and providing the inner member with a radially extending  
20 ridge having the second radially extending surface.
18. The method of claim 17, comprising forming the retaining  
portion as a circumferential ridge.
- 25 19. The method of claim 18, comprising forming the  
circumferential ridge integrally with the outer tube.
20. The method of claim 17, comprising forming the retaining  
portion as a plurality of protuberances, each protuberance  
30 circumferentially spaced from an adjacent protuberance.

21. The method of claim 16, further comprising providing the outer tube with a slot having the first radially extending surface and providing the inner member includes a radially extending ridge disposed within the slot.

5

22. The method of claim 21, comprising providing the outer tube with a third radially extending surface positioned proximally of the first radially extending surface and providing the inner member with a fourth radially extending surface positioned proximally of the third  
10 radially extending surface.

23. The method of claim 16, wherein the retaining portion is formed by corsetting the outer tube.

15 24. The method of claim 16, wherein the retaining member is formed by laminating a member to the outer tube.

25. A surgical tool for use with a surgical instrument having an inner member positioned within a central bore of an outer tube, the  
20 outer tube having a first radially extending surface in the bone, the surgical tool comprising a body adapted to be positioned on the distal end of the inner member and having a second radially extending surface positioned to contact the first radially extending surface of the outer tube to maintain the surgical tool within the  
25 central bore if the surgical tool separates from the inner member.



FIG. 1.

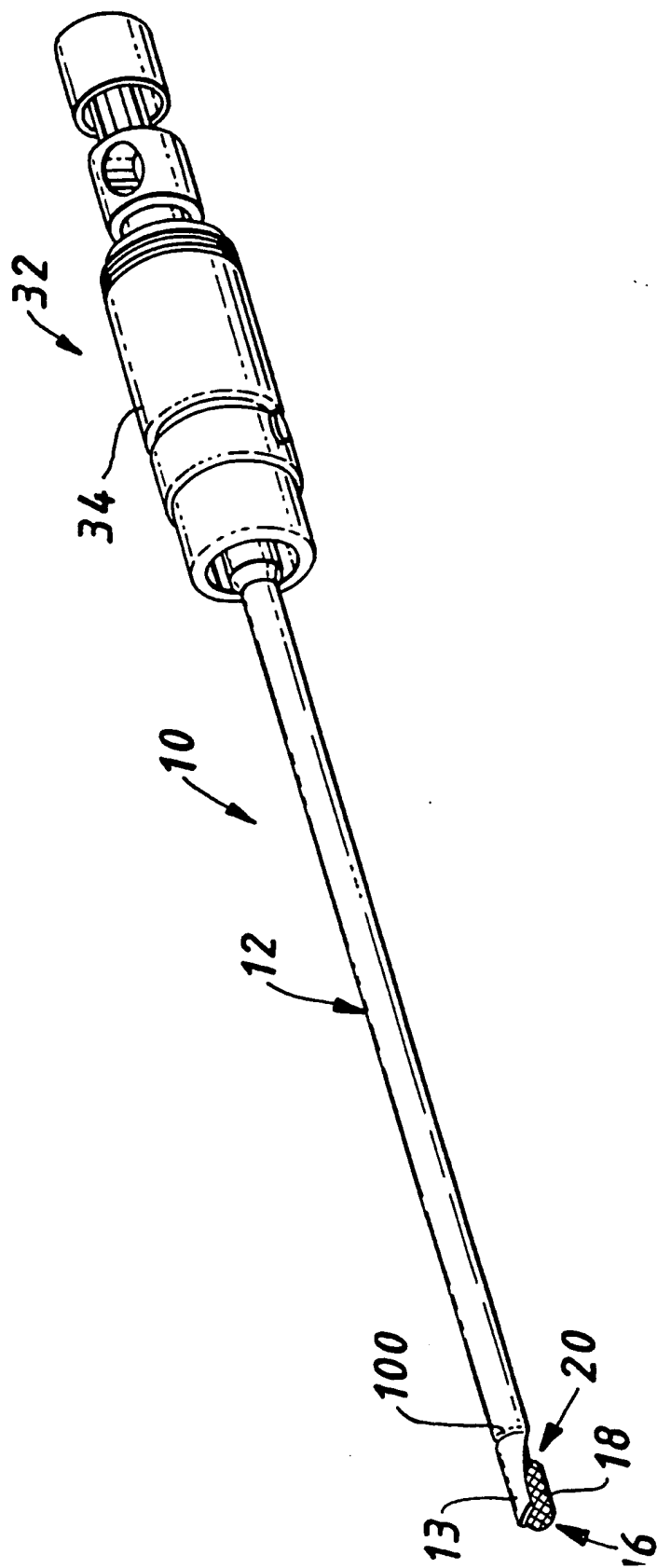
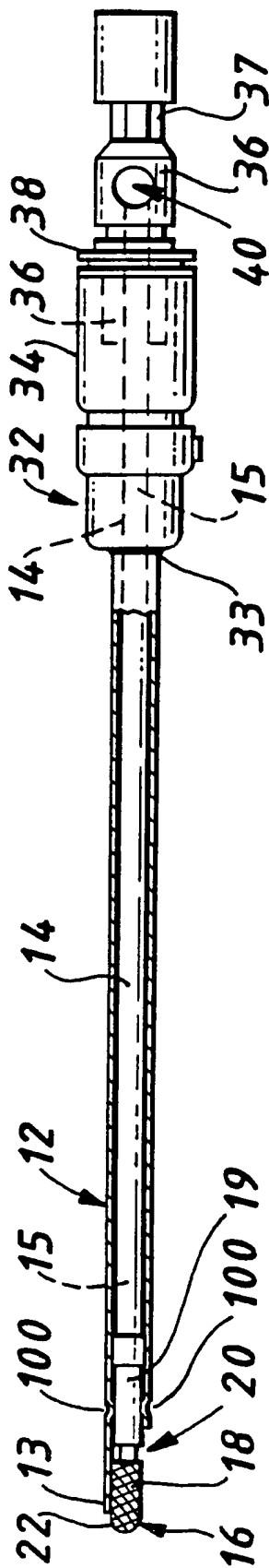
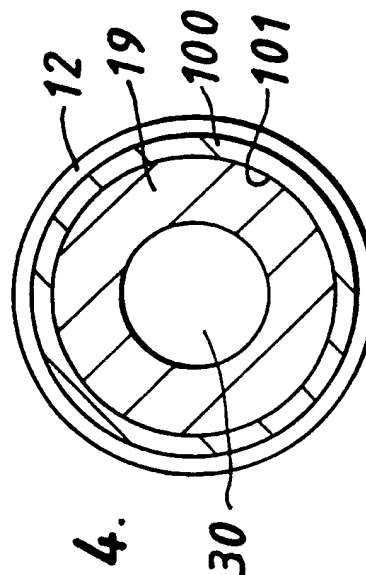
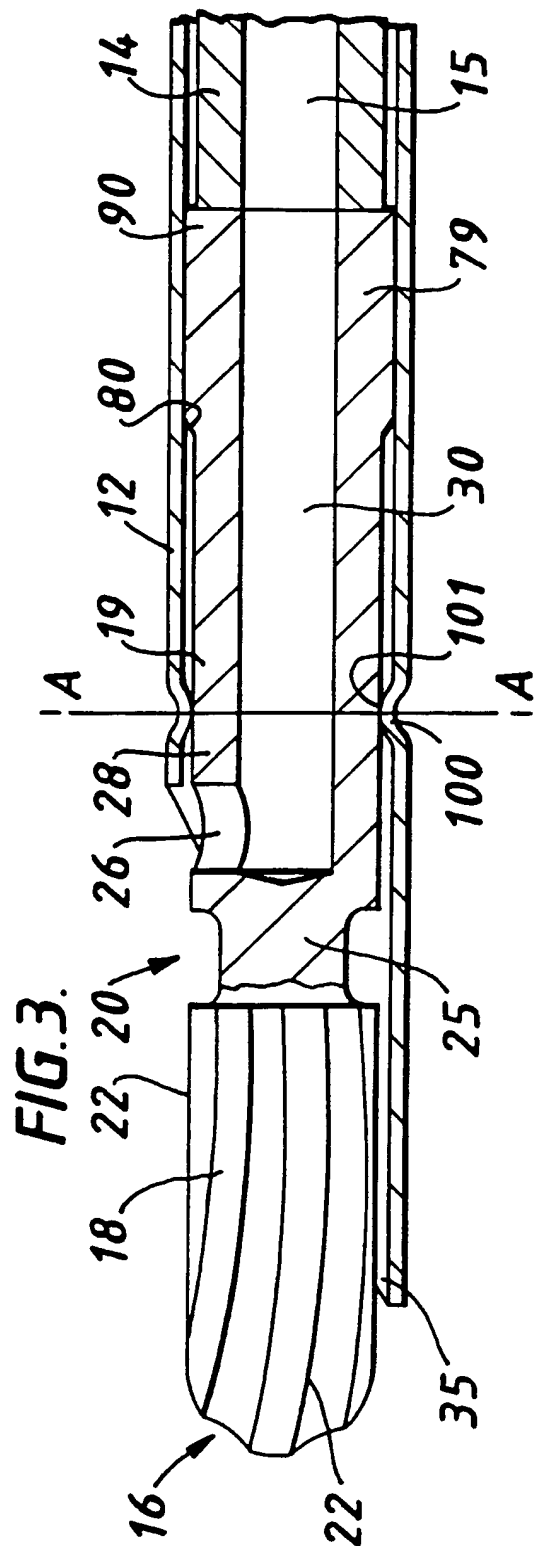
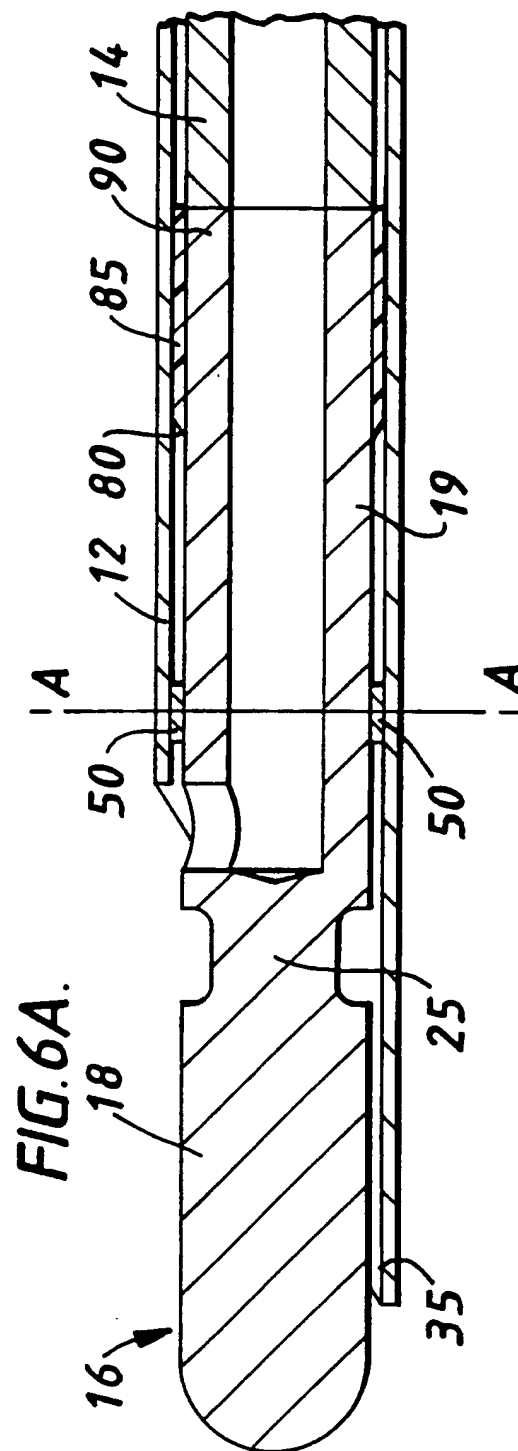
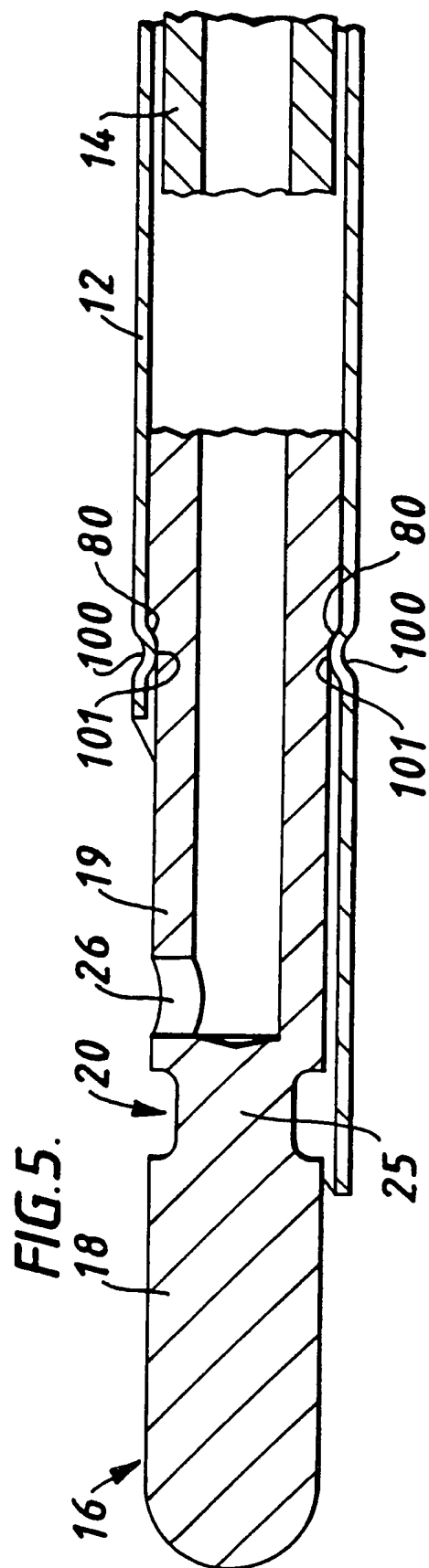


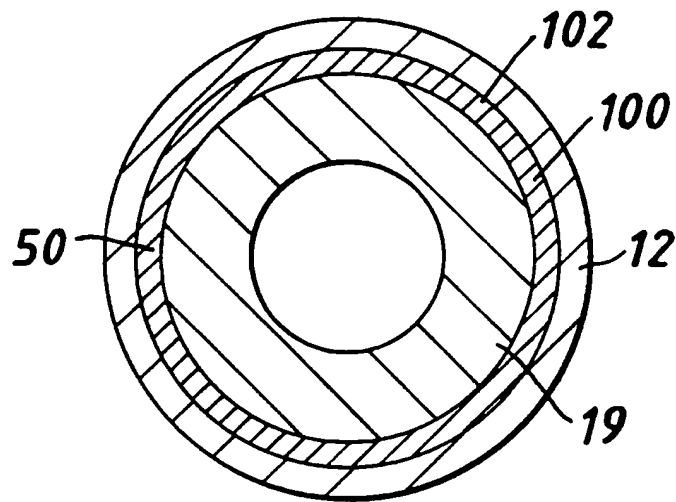
FIG. 2.



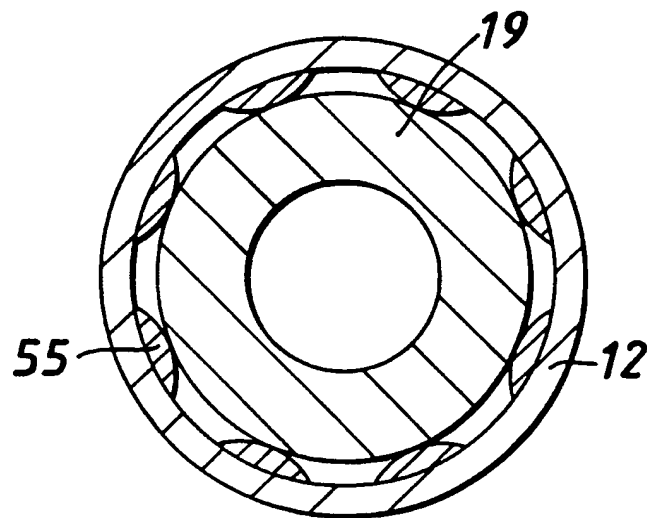




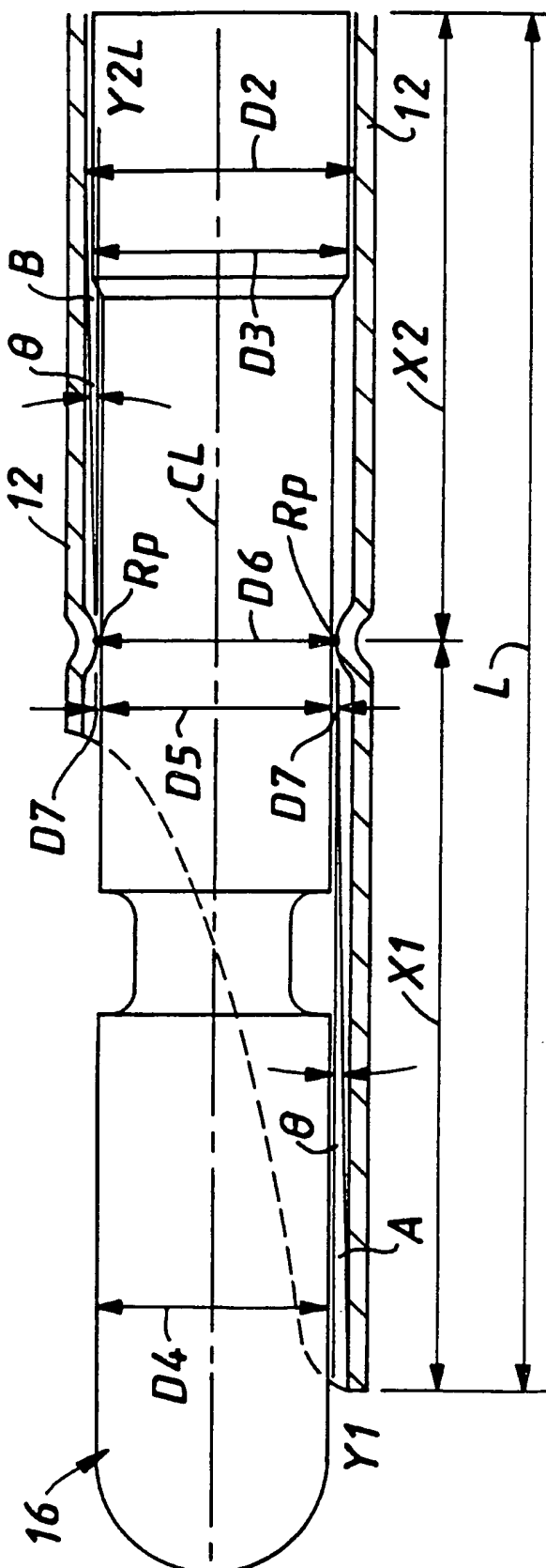
**FIG. 6B.**

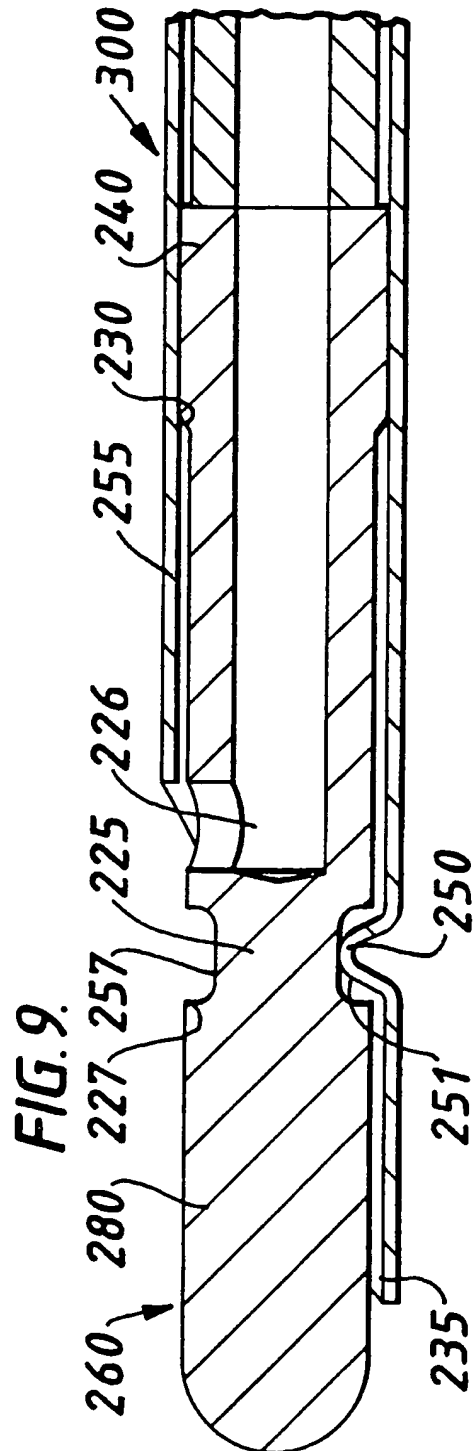
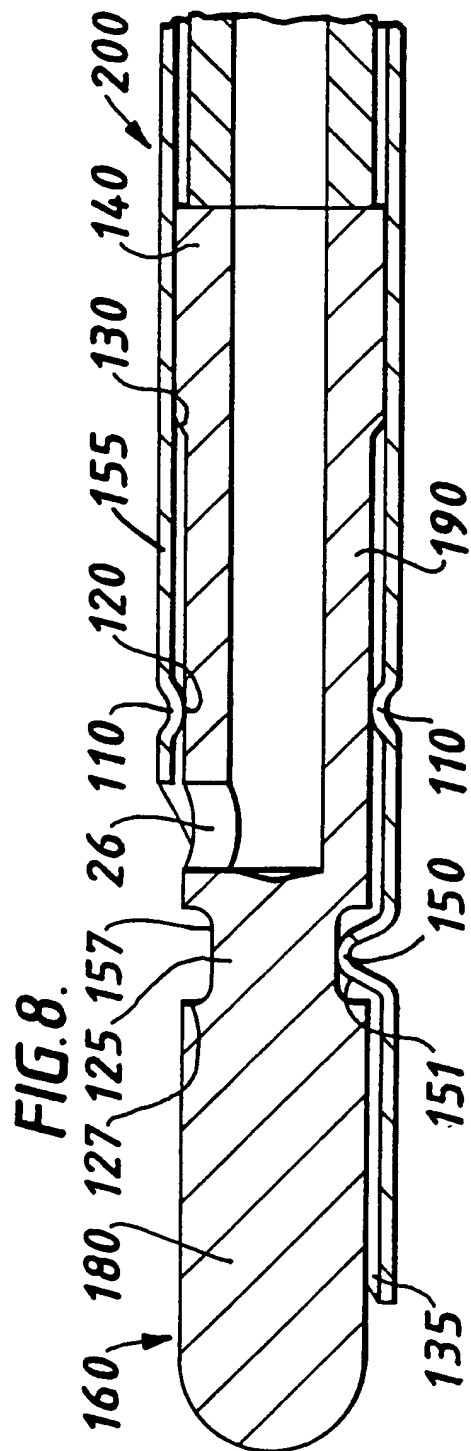


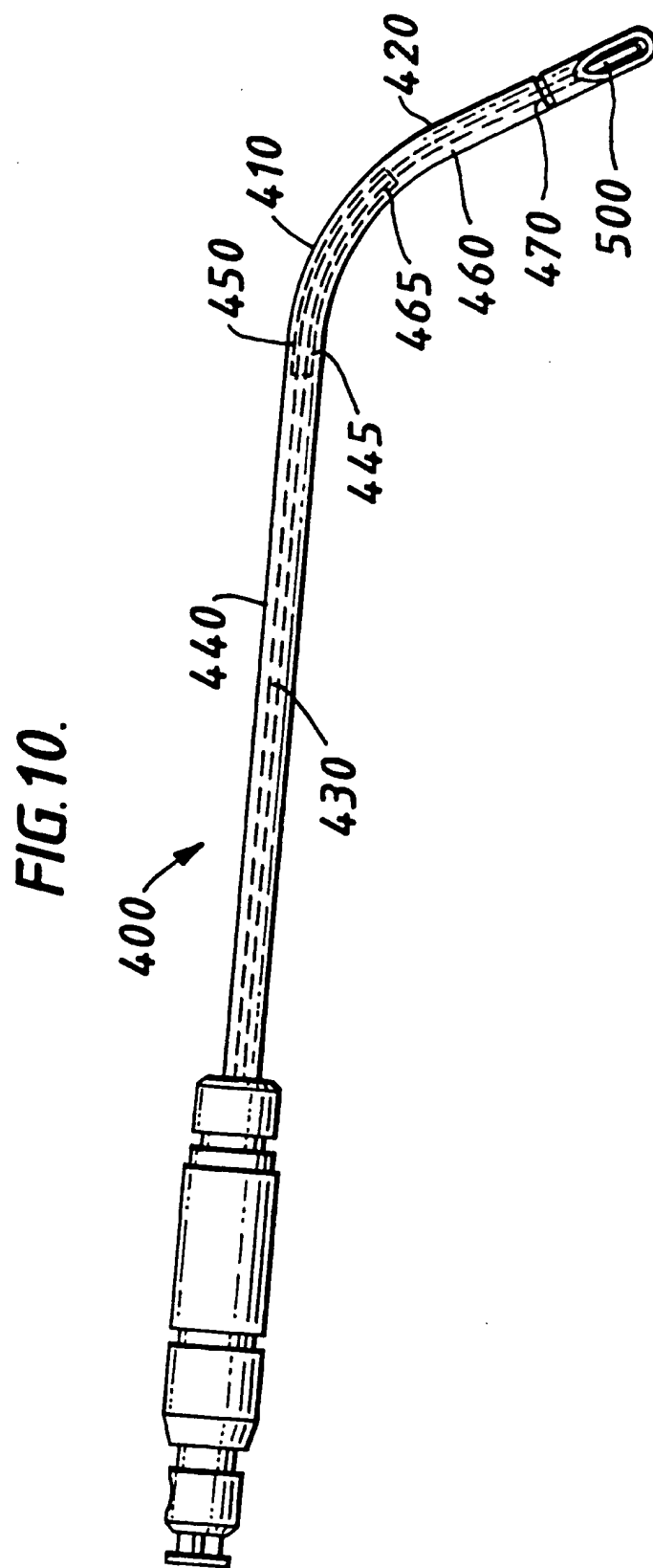
**FIG. 6C.**



**FIG. 7.**









# INTERNATIONAL SEARCH REPORT

International Application No  
PCT/US 00/25068

## A. CLASSIFICATION OF SUBJECT MATTER

IPC 7 A61B17/32

According to International Patent Classification (IPC) or to both national classification and IPC

## B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)  
IPC 7 A61B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

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## C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 5 123 904 A (SHIMOMURA) 23 June 1992 (1992-06-23)	1-5, 8, 13-15, 25
Y	column 4, line 47 - line 63; figures 3, 4, 6, 7, 16	6, 7, 19
X	US 5 257 990 A (NASH) 2 November 1993 (1993-11-02)	1-4, 8, 14, 15, 25
Y	column 4, line 14 - column 5, line 33; figures 1, 2	23
X	WO 92 15255 A (BOWEN) 17 September 1992 (1992-09-17)	1, 8, 13-18, 24, 25
Y	page 7, line 27 - page 8, line 6 page 11, line 31 - page 13, line 6; figures 2, 8	19, 20, 23
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☒ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

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Date of the actual completion of the international search

11 December 2000

Date of mailing of the international search report

19/12/2000

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# INTERNATIONAL SEARCH REPORT

International Application No  
PCT/US 00/25068

## C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US 5 405 348 A (ANSPACH) 11 April 1995 (1995-04-11) column 4, line 30 -column 5, line 40; figures 3-10 ---	6,7,20
A	GB 2 093 353 A (DYONICS INC.) 2 September 1982 (1982-09-02)  page 3, line 35 - line 127; figures 2,2A,3 -----	1-4,8, 10, 13-18,25

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International Application No  
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